

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

REC'D 04 MAR 2005

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 227-03980		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/IL2004/000289		International filing date (day/month/year) 29.03.2004	Priority date (day/month/year) 01.04.2003	
International Patent Classification (IPC) or national classification and IPC A61B5/00, G01N21/17				
Applicant GLUCON INC. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 01.11.2004		Date of completion of this report 02.03.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Lohmann, S Telephone No. +49 89 2399-2328		



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-19 as originally filed

Claims, Numbers

6-28 as originally filed
1-5 filed with telefax on 01.11.2004

Drawings, Sheets

1/2-2/2 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-28
	No: Claims	
Inventive step (IS)	Yes: Claims	1-28
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-28
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V.

1 The following documents are referred to in this communication:

- D1: US-B-6 405 069 (KARABUTOV ALEXANDER A ET AL) 11 June 2002
D2: US-B-6 498 942 (ESENALIEV RINAT O ET AL) 24 December 2002
D3: MOURANT J R ET AL: "Mechanisms of light scattering from biological cells relevant to noninvasive optical-tissue diagnostics" APPL. OPT., 1 JUNE 1998, OPT. SOC. AMERICA, USA, vol. 37, no. 16, 1 June 1998, pages 3586-3593, XP001182699 ISSN: 0003-6935.

2 The present application meets the requirements of Article 33(1) PCT, because the subject-matter of independent claims 1 and 15 is new and inventive under Articles 33(2) and (3) PCT.

2.1 Document D1 is regarded as being the closest prior art to the subject-matter of claims 1 and 15 and discloses an apparatus and a method from which the subject-matter of claims 1 and 15 differs in the step of determining the concentration of the target analyte **responsive to a solution of a set of simultaneous equations** (claim 15) and a corresponding controller (claim 1).

The subject-matter of claims 1 and 15 is therefore new (Article 33(2) PCT).

2.2 By means of the aforementioned distinguishing feature, an alternative way of determining the concentration of the target analyte is provided, in contrast to the **fitting algorithms** taught by D1 (col. 4, l. 9-42).

Document D2 does not suggest consideration of the reduced scattering coefficient because of its negligibility compared to the absorption coefficient in case of the described purpose of cerebral measurements (col. 10, l. 29-32 and col. 11, l. 1-4).

Although both D1 and D2 teach a plurality of wavelengths and D3 discusses a wavelength dependence of the reduced scattering coefficient (for different **particle sizes** in suspensions only), an assessment according to which a skilled person **would** use a

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set of simultaneous equations as claimed would benefit from hindsight, since said wavelength dependence could also be taken into account in the aforementioned fitting algorithms for each wavelength individually.

Therefore, the subject-matter of claims 1 and 15 is considered to involve an inventive step under Article 33(3) PCT.

- 2.3 Claims 2-14 and 16-28 are dependent on claims 1 and 15, respectively, and as such also meet the requirements of the PCT with respect to novelty and inventive step.

227-03980

CLAIMS

1. Apparatus for assaying a target analyte in a localized tissue region that may include the target and other analytes comprising:

5 a light source that illuminates the region with light at each of a plurality of wavelengths at which light is absorbed and/or scattered by tissue in the region wherein light at at least one of the wavelengths is absorbed ~~ex~~ and/or scattered by the target analyte;

a signal generator that generates signals responsive to intensity of the light from the light source at different locations in the localized region; and

a controller that:

10 receives the generated signals;

processes the signals to determine an extinction coefficient for light in the localized region at each wavelength; and

15 determines the concentration of the target analyte responsive to a solution of a set of simultaneous equations having as unknown variables concentrations of a plurality of analytes in the region, one of which is the target analyte, wherein each equation in the set expresses a relationship between the extinction coefficient, the absorption coefficient and/or the reduced scattering coefficient for light at a different one of the plurality of wavelengths and at least one of the equations expresses a relationship between the extinction coefficient and the reduced scattering coefficient.

20 2. Apparatus according to claim 1 wherein the at least one equation that expresses a relationship between the extinction coefficient and the reduced scattering coefficient includes a dependence on the absorption coefficient.

25 3. Apparatus according to claim 1 or claim 2 wherein the reduced scattering coefficient at at least one of the wavelengths is a measured value of the reduced scattering coefficient.

4. Apparatus according to any of claims 1-3 wherein the reduced scattering coefficient at least one of the wavelengths is a value determined responsive to an analytic expression.

30 5. Apparatus according to any of claims 1-4 wherein the reduced scattering coefficient at at least one of the wavelengths is expressed as an analytic function.